

Pennsylvania Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 390049	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____		(X3) DATE SURVEY COMPLETED: 07/28/2023
NAME OF PROVIDER OR SUPPLIER: ST. LUKE'S WEST END ENDOSCOPY CENTER STATE LICENSE NUMBER: 24351501		STREET ADDRESS, CITY, STATE, ZIP CODE: 501 CETRONIA RD. ALLENTOWN, PA 18104			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE	(X5) COMPLETE DATE	
S 0000	INITIAL COMMENT	S 0000			
S 0043	This report is the result of a State licensure survey conducted on July 28, 2023, at St. Luke's West End Endoscopy Center. It was determined the facility was not in compliance with the requirements of the Pennsylvania Department of Health's Rules and Regulations for Ambulatory Care Facilities, Annex A, Title 28, Part IV, Subparts A and F, Chapters 551-573, November 1999.	S 0043			
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE			TITLE:		(X6) DATE:

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S 0043	Continued from page 1 51.31 Exceptions - Principle 51.31. Principle The Department may grant exceptions to this part when the policy and objectives contained therein are otherwise met, or when compliance would create an unreasonable hardship and an exception would not impair or endanger the health, safety or welfare of a patient or resident. No exceptions or departures from this part will be granted if compliance with the requirement is provided for by statute. This REGULATION is not met as evidenced by:	S 0043	The Administrator of West End Endoscopy, the Director of Nursing, and the Quality Director will be educated that the activities of the center must be reflected in the governing body minutes of St. Luke's University Health Network. The Administrator of West End Endoscopy will be responsible for the plan of correction. The Administrator of West End Endoscopy or designee will provide a report to the board regarding the activities of the center on an annual basis. Annually, the Administrator of West End Endoscopy will submit a report regarding the activities of the center to the Director of Accreditation and Standards to ensure compliance.	Completion Date: 10/06/2023 Status: APPROVED Date: 08/23/2023	

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S 0043	<p>Continued from page 2</p> <p>Based on a review of facility documents and interview with staff (EMP), it was determined the facility failed to comply with required criteria as stated in the exception granted by the Department for 28 Pa Code § 553.1. St. Luke's West End Endoscopy (ASF) failed to ensure the activities of the ASF were reported to the governing body of St. Luke's Health Network.</p> <p>Findings include:</p> <p>Review on July 28, 2023, of a letter from the Department November 20, 2015, revealed "The request related to Governing Body (28 Pa. Code § 553.1) is granted based on the information provided in the narrative submitted. St. Luke's West End Endoscopy (ASF) must be specifically addressed in the St. Luke's Health Network (SLHN) bylaws of the governing body. All the bylaws of The SLHN will apply to the ASF unless specifically stated otherwise. The governing body minutes must reflect the activities of the ASF. The minutes that relate to</p>	S 0043			

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S 0043	Continued from page 3 the ASF must be maintained at the ASF ..." A request was made on July 28, 2023, to EMP1 for the facility's governing body meeting minutes. EMP1 provided the following documents: "St. Luke's Allentown Campus, Board of Governors Meeting" minutes, dated August 18, 2022, December 15, 2022, March 16, 2023, June 15, 2023." Interview on July 28, 2023, at approximately 11:20 AM with EMP1 confirmed the activities of the facility are reported to St. Luke's Allentown Campus, Board of Governors and confirmed they do not report facility activites to St. Luke's Health Network governing body.	S 0043			

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S 0043	Continued from page 4	S 0043			
S 033A		S 033A			

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S 033A	Continued from page 5 553.3 (1) Governing Body Responsibilities 553.3 Governing Body responsibilities include: (1) Conforming to all applicable Federal, State, and local laws. This REGULATION is not met as evidenced by:	S 033A	The Administrator of West End Endoscopy and the Patient Safety Officer will be educated that investigation reports and actions taken to promote patient safety must be submitted quarterly to the governing body. The Patient Safety Officer will be responsible for providing investigation reports and the actions taken to promote patient safety at the ASF quarterly to the governing body. The Administrator will be responsible for ensuring that the investigation reports, including actions taken have been submitted to the board quarterly. Quarterly, the Administrator will submit the patient safety meeting minutes to the Coordinator of Accreditations & Standards to ensure compliance. The Administrator will be responsible for the plan of correction. Quarterly, the Administrator will be responsible to	Completion Date: 10/06/2023 Status: APPROVED Date: 08/23/2023	

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S 033A	Continued from page 6	S 033A	ensure a report has been submitted to the board regarding patient safety events and investigations at the center.		

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S 033A	<p>Continued from page 7</p> <p>Based on review of facility documents and staff interview (EMP), it was determined the facility failed to conform to applicable state laws.</p> <p>St. Luke's West End Endoscopy Center was not in compliance with the following State Law:</p> <p>Act 13 of 2002 Medical Care Availability and Reduction of Error (MCARE) Act, Chapter 3. Patient Safety Section 309. Patient safety officer. A patient safety officer of a medical facility shall do all of the following ... (5) Report to the administrative officer and governing body of the medical facility on a quarterly basis regarding the number of serious events and incidents and its recommendations to eliminate future serious events and incidents ... "</p> <p>This is not met as evidenced by:</p> <p>Based on review of facility documents, and staff interview (EMP), it was determined the facility failed</p>	S 033A			

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S 033A	Continued from page 8 to report serious events and incidents to the governing body quarterly. Findings include: Review on July 28, 2023, of facility document "Patient Safety Plan, St. Luke's West End Endoscopy Center," revised 7/25/22, revealed "Patient Safety Committee... Report to President and Chief Executive Officer and the Board of Trustees on a quarterly basis regarding the number of serious events and incidents ..." Review on July 28, 2023, of facility document "St. Luke's Allentown Campus, Board of Governors Meeting" minutes, dated August 18, 2022, December 15, 2022, March 16, 2023, June 15, 2023, revealed no documentation the governing body received or reviewed quarterly reports regarding the number of serious events and incidents.	S 033A			

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S 3230	Continued from page 10 553.23 Discharge by transfer 553.23 Discharge by transfer Prior arrangements made for admissions. Clinical records shall accompany the patient. This REGULATION is not met as evidenced by:	S 3230	The Medical Director of West End Endoscopy will be responsible in educating all providers that when an emergency occurs and a patient must be transferred to another facility, the receiving facility must be notified of the transfer. The Medical Director of West End Endoscopy will also educate all providers that they must document this notification in the patient's electronic medical record. The Administrator of West End Endoscopy will develop an inter-hospital AVS which will include all pertinent information regarding the patient's stay at the ASF. The Administrator will educate staff members that the inter-hospital AVS must be sent with the patient to the receiving facility. The Director of Nursing or designee will be responsible for performing audits of electronic medical records of all transfers from West End Endoscopy to ensure there is documentation that the receiving facility was notified of the transfer	Completion Date: 10/06/2023 Status: APPROVED Date: 08/23/2023	

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S 3230	Continued from page 11	S 3230	<p>and that the inter-hospital AVS was sent with the patient. These audits will be reviewed with the Administrator of West End Endoscopy and will be reviewed at the quarterly Quality/PI committee meeting.</p> <p>The Administrator of the ASC will be responsible for the plan of correction and will review audit results at the quarterly Quality/PI committee meeting. Additionally, the Administrator will be responsible for providing a report to the board regarding annually regarding patient safety events and investigations at the Anderson Ambulatory Surgery Center.</p>		

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S 3230	Continued from page 12 Based on a review of facility policy, medical records (MR) and interview with staff (EMP), it was determined the facility failed to document prior arrangements were made for patient transfers to receiving facilities and failed to document medical records were provided to the receiving facility for 4 of 10 medical records reviewed. (MR1, MR2, MR4, MR5) Findings include: Review on July 28, 2023, of facility policy "Operational Guidelines" reviewed July 2021, revealed "... The Patient Access Center will be called and given patient information and will inform St. Luke's Allentown of a patient transfer ..." Further review revealed no documentation the medical records should be provided to the receiving facility. Review on July 28, 2023, of MR1 revealed the patient presented to the surgery center for a surgical	S 3230			

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S 3230	Continued from page 13 procedure on December 15, 2022, and experienced an event that required the transfer to a higher level of care. Further review revealed no documentation the receiving facility was notified of the transfer and no documentation medical records were provided to the receiving facility. Review on July 28, 2023, of MR2 revealed the patient presented to the surgery center for a surgical procedure on February 17, 2023, and experienced an event the required the transfer to a higher level of care. Further review revealed no documentation medical records were provided to the receiving facility. Review on July 28, 2023, of MR4 revealed the patient presented to the surgery center for a surgical procedure on April 27, 2023, and experienced an event that required the transfer to a higher level of care. Further review revealed no documentation the receiving facility was notified of the transfer and no	S 3230			

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S 3230	Continued from page 14 documentation medical records were provided to the receiving facility. Review on July 28, 2023, of MR5 revealed the patient presented to the surgery center for a surgical procedure on May 5, 2023, and experienced an event that required the transfer to a higher level of care. Further review revealed no documentation the receiving facility was notified of the transfer and no documentation medical records were provided to the receiving facility. Interview on July 28, 2023, with EMP1 at approximately 12:00 PM confirmed MR1, MR2, MR4 and MR5 were transferred to a higher level of care and confirmed there was no documentation the receiving facility was notified and no documentation clinical records were provided.	S 3230			
S 331A		S 331A			

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S 331A	Continued from page 15 553.31 (a) Administrative responsibilities A full time person in charge shall be appointed who has authority and responsibility for the operation of the ASF at all times. Qualifications, authority, responsibilities and duties of the person in charge shall be defined in a written statement adopted by the governing body. This REGULATION is not met as evidenced by:	S 331A	The Clinical Coordinator will be designated as the Administrator of West End Endoscopy. Due to this change, the ASF's charge nurse will be designated as the Director of Nursing. The DOH license application will be changed to reflect the new administrator and director of nursing. Notice of the change will also be sent to the Department of Health as per regulation 51.4c Change in ownership; change in management. As needed, but minimally prior to the annual licensure, the Administrator of West End Endoscopy will review leadership roles to ensure the Department of Health's regulations are met. Results of the review will be reported to the Quality/PI Committee of the ASF as well as up to and including the Governing Body who will be responsible for any plan of correction.	Completion Date: 10/06/2023 Status: APPROVED Date: 08/23/2023	

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S 331A	Continued from page 16 Based on observation, review of facility documents, and interview with staff (EMP), it was determined the facility failed to ensure that a full-time person was in charge that had the authority and responsibility for the operation of St. Luke's West End Endoscopy Center at all times. Findings include: Review on July 28, 2023, of facility document "Amended and Restated Bylaws of Saint Luke's Hospital of Bethlehem, Pennsylvania" revealed "... To establish and maintain facilities, personnel and services for the care of persons suffering from illnesses, diseases and disabilities and the diagnosis thereof, including full legal authority and responsibility for the conduct of the St. Luke's West End Endoscopy Center in accordance with the regulations of the Pennsylvania Department of Health ..."	S 331A			

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S 331A	<p>Continued from page 17</p> <p>Review on July 28, 2023, of the facility license application "Ambulatory Surgical Facility Application Request Form" dated July 24, 2023, revealed EMP3 was identified as the Administrator for the facility.</p> <p>Review on July 28, 2023, of facility document "Clinical Coordinator" dated May 23, 2023, for EMP1, revealed "... The Clinical Coordinator is responsible for planning, coordinating, directing and evaluating daily operations and guiding the unit based team ..."</p> <p>Interview on July 28, 2023, at approximately 10:00 AM with EMP1 confirmed they are the administrator of the endoscopy center and oversee the daily operations. Further interview with EMP1 confirmed EMP3 was identified as the administrator on the license application and confirmed EMP3 does not have the authority and responsibility to</p>	S 331A			

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S 331A	Continued from page 18 oversee the surgery center.	S 331A			



Certified End Page

ST. LUKE'S WEST END ENDOSCOPY CENTER

STATE LICENSE NUMBER: 24351501

SURVEY EXIT DATE: 07/28/2023

**I Certify This Document to be a True and Correct Statement of Deficiencies and
Approved Facility Plan of Correction for the Above-Identified Facility Survey**

A handwritten signature in black ink that reads "Jeane Parisi".

Jeane Parisi
Deputy Secretary for Quality Assurance

A handwritten signature in black ink that reads "Debra L. Bogen MD".

Debra L. Bogen, MD, FAAP
Acting Secretary of Health



THIS IS A CERTIFICATION PAGE

PLEASE DO NOT DETACH

THIS PAGE IS NOW PART OF THIS SURVEY